



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day-19-0048; Docket No. ATSDR-2018-0009]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Agency for Toxic Substance and Disease Registry,
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Agency for Toxic Substance and Disease Registry, as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ATSDR Exposure Investigations (EIs) (OMB Control No. 0923-0048, Expiration Date 3/31/2019) - Extension - Agency for Toxic Substances and Disease Registry (ATSDR). To evaluate public health issues at a site resulting from environmental exposure, ATSDR EIs fill data gaps by conducting environmental and biological sampling.

DATES: CDC must receive written comments on or before [INSERT
DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2018-0009 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact *Jeffrey M. Zirger*, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition,

the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

ATSDR Exposure Investigations (EIs) (OMB Control No. 0923-0048, Expiration Date 3/31/2019) - Extension - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act approval for the extension of the generic clearance titled ATSDR Exposure Investigations (OMB No. 0923-0048; OMB Exp. Date: 3/31/2019) to allow the agency to conduct exposure investigations (EIs), through methods developed by ATSDR.

After a chemical release or suspected release into the environment, EIs are usually requested by officials of a state health agency, county health departments, the Environmental Protection Agency (EPA), the public, and ATSDR staff.

EI results are used by public health professionals, environmental risk managers, and other decision makers to determine if current conditions warrant intervention

strategies to minimize or eliminate human exposure. For example, four of the EIs that ATSDR conducted in the past three years include the Anaconda Smelter (MT - blood lead and urine arsenic), Former United Zinc and Associated Smelters (KS - blood lead), Dimock Private Well Water Sampling (PA) and Follow-up arsenic urine testing in Hayden, Arizona.

Example 1: Anaconda Smelter Blood Lead and Urine Arsenic Sampling, MT

The site is a former smelter located in Anaconda, Montana. Past smelting activities resulted in high levels of heavy metals, primarily arsenic and lead, in community soil and in the slag piles. ATSDR sampled blood and urine in community members to evaluate lead (blood) and arsenic (urine). Given community concern about contamination, all members of the community were invited to participate in the testing.

Urine samples were evaluated for total arsenic, speciated arsenic (organic and inorganic), creatinine and specific gravity. If arsenic is detected, speciation of the sample will determine whether the arsenic is organic (probably resulting from eating seafood) or inorganic (likely resulting from exposure to environmental arsenic). The results of the testing are currently being analyzed by the National Center for

Environmental Health/Division of Laboratory Sciences (NCEH/DLS). Results will be sent individually to participants when the analysis is completed and a report will be prepared and presented to the community in a community meeting.

Example 2: Former United Zinc and Associated Smelters blood lead testing, Iola, Kansas

The community is located in the vicinity of the Former United Zinc and Associated Smelters in Iola, Kansas. The smelters operated from 1902 to 1925 and operations resulted in heavy metal contamination in community soils. Limited sampling of the community in the past found elevated blood lead levels in young children. The blood testing was completed in two phases: one in December of 2016 and one in August 2017 and a total of 61 participants were tested: 24 children younger than 6 years, 17 children aged 6-19 years and 20 adult women. One child younger than 6 years had a BLL greater than 5 µg/dL. The child's parents were notified by phone of the results by the ATSDR Medical Officer and follow up was conducted by the local PEHSU (Pediatric Environmental Health Specialty Unit).

All participants received their results by mail and the EI report was released and presented to the community in a public meeting in August 2018.

Example 3: Private Well Water Sampling in Dimock, Pennsylvania

Unconventional natural gas drilling activities have been conducted in the Dimock, PA area for approximately 10 years and local residents complain of poor water quality. In 2012, EPA sampled 64 private wells in the area for contaminants that may be present due to natural gas drilling activities. ATSDR assisted in the analysis of the 2012 data set and the following recommendations were made:

- o people with elevated levels of inorganic analytes in their well water should install a home treatment system, and
- o people with high levels of methane in their well water should vent their well and home and treat their water to eliminate potential buildup of explosive gases.

Example 4: Follow-up arsenic urine testing in Hayden, Arizona

ATSDR completed an EI in 2015 at the ASARCO Hayden Smelter Site in Hayden, AZ. The EI included blood lead and urine arsenic testing. Air monitoring determined that the smelter was not operating during the sample collection period and that, given the short half-life of

arsenic in the body, the arsenic results may not be valid.

In 2017, ATSDR retested the participants from the 2015 EI to evaluate their urinary arsenic levels. It was determined that all urinary arsenic levels were below the follow-up level and air data indicate that air arsenic levels in the 2 weeks prior to testing were consistent with usual levels seen in the community. The EI report is being prepared and a community meeting will be held when the document is released.

Additional water sampling was recommended and an EI was conducted in August in 2017. For the EI, the 64 residents previously sampled were invited to have their private wells retested: 25 residences agreed participate in the EI sampling. Residents were provided the results of their sampling and an EI report is currently being prepared. It will be presented to the community in a public meeting when completed.

All of ATSDR's targeted biological assessments (e.g., urine, blood) and some of the environmental investigations (e.g., air, water, soil, or food sampling) involve participants to determine whether they are or have been exposed to unusual levels of pollutants at specific locations (e.g., where people live, spend

leisure time, or anywhere they might come into contact with contaminants under investigation).

Questionnaires, appropriate to the specific contaminant, are generally needed in about half of the EIs (at most approximately 12 per year) to assist in interpreting the biological or environmental sampling results. ATSDR collects contact information (e.g., name, address, phone number) to provide the participant with their individual results. ATSDR also collects information on other possible confounding sources of chemical(s) exposure such as medicines taken, foods eaten, hobbies, jobs, etc. In addition, ATSDR asks questions on recreational or occupational activities that could increase a participant's exposure potential. That information represents an individual's exposure history.

The number of questions can vary depending on the number of chemicals being investigated, the route of exposure (e.g., breathing, eating, touching), and number of other sources of the chemical(s) (e.g., products used, jobs). We use approximately 12-20 questions about the pertinent environmental exposures per investigation. Typically, the number of participants in an individual EI ranges from 10 to 100. Participation is completely

voluntary, and there are no costs to participants other than their time. Based on a maximum of 12 EIs per year and 100 participants each, the estimated annualized burden hours are 600.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Exposure Investigation Participants	Chemical Exposure Questions	1,200	1	30/60	600
Total					600

Jeffrey M. Zirger,

Acting Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2018-24234 Filed: 11/5/2018 8:45 am; Publication Date: 11/6/2018]